UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

SHARON BRODIE, Surviving Spouse and Executor of the Estate of JOHN BRODIE, Deceased,	)	
Plaintiff,	)	
vs.	)	Case No. 4:10-CV-138 (HEA)
NOVARTIS PHARMACEUTICALS CORPORATION,	)	
Defendant.	)	

NOVARTIS PHARMACEUTICALS CORPORATION'S
MOTION FOR JUDGMENT AS A MATTER OF LAW ON ALL CLAIMS

Novartis Pharmaceuticals Corporation ("NPC") moves for judgment as a matter of law on all claims pursuant to Federal Rule of Civil Procedure 50(a). Plaintiff Sharon Brodie has been fully heard and has failed to put forth sufficient evidence to carry her burden of proof.

Plaintiff brought this action for strict liability, negligence, and breach of warranty alleging that her husband, John Brodie, developed osteonecrosis of the jaw ("ONJ") caused by the drug Zometa®. She proceeds on a failure to warn theory only. Plaintiff purports to have proven that (a) NPC's August 2004 label should have differed in some material regard, (b) if NPC had given a different warning, Mr. Brodie's oncologist, Dr. Paul Schultz, would have treated Mr. Brodie differently, and (c) that different treatment would have either prevented or mitigated Mr. Brodie's ONJ.

Judgment as a matter of law should be granted to NPC under Federal Rule of Civil Procedure 50(a) because plaintiff has not presented evidence sufficient to get to a jury on any of these elements.

FACTUAL STATEMENT

Zometa® was first approved by the Food and Drug Administration in 2001 and is indicated for the treatment of patients with hypercalcemia of malignancy, multiple myeloma, and bone metastases of solid tumors (including prostate cancer). *See* Zometa® label, PX-1178 (attached as Exhibit 1). Because it is given to cancer patients, Zometa® is most commonly prescribed by oncologists, like Dr. Schultz. In September 2003, NPC updated the Zometa® label to include references to cases of ONJ occurring in users of Zometa®. NPC revised the Zometa® label again in February 2004 and in August 2004. In September 2004, NPC mailed a Dear Doctor letter to over 17,200 physicians, including Dr. Schultz, to alert them of the risk of ONJ as reflected in the August 2004 Zometa® label. As this Court has recognized, NPC's duty to warn about the risks associated with Zometa® ran only to prescribing physicians, in this case, Dr. Schultz. Order, ECF No. 173.[1]

The September 24, 2004 Dear Doctor letter, which quoted the August 2004 label, in pertinent part, reads as follows:

[1] *See also Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 146, 151 (Mo. 1967) (the manufacturer of a prescription drug "has a duty to properly warn *the doctor* of the dangers involved"; "the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer") (emphasis added); *Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670, 671 (8th Cir. 1985) ("warning to the doctor is deemed a warning to the patient"); *Hill v. Wyeth, Inc.*, No 4:03-CV-1526, 2007 WL 674251 at *3-4 (E.D. Mo. Feb. 28, 2007).

> **PRECAUTIONS**
>
> **Osteonecrosis of the jaw (ONJ) has been reported in patients with cancer receiving treatment regimens including bisphosphonates.** Many of these patients were also receiving chemotherapy and corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. Many had signs of local infection including osteomyelitis.
>
> A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g. cancer, chemotherapy, corticosteroids, poor oral hygiene).
>
> While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition.

NPC's September 24, 2004 Dear Doctor Letter, PX-1190 (attached as Exhibit 2)

(emphasis added).

The following facts are now undisputed:[2]

- Dr. Schultz received the Dear Doctor letter in the fall of 2004, which was before he saw Mr. Brodie. Trial Tr. Vol. 3B at 67:9-13 (Transcript excerpts attached as Exhibit 3).

- In response, Dr. Schultz and his colleagues had a discussion about the new information regarding ONJ. Trial Tr. Vol. 3B at 74:10-16.

[2] The Court may consider all of the evidence in the record and "give credence to the evidence favoring the nonmovant as well as that 'evidence supporting the moving party that is uncontradicted and unimpeached, at least to the extent that that evidence comes from disinterested witnesses.'" *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 151 (2000) (quoting 9A C. Wright & A. Miller, Federal Practice and Procedure § 2529, p. 299 (2d ed. 1995)); *see also Penford Corp. v. Nat'l Union Fire Ins. Co. of Pittsburgh, Pa.*, 662 F.3d 497, 507-09 (8th Cir. 2011) (recognizing that court may consider testimony from disinterested witnesses and witnesses who are arguably interested parties where testimony is uncontradicted and unimpeached).

- Dr. Schultz and his colleagues concluded that they would continue to prescribe Zometa® because the benefits of Zometa® outweigh the risk of ONJ. Trial Tr. Vol. 3B at 85:11-13.

- Mr. Brodie began seeing Dr. Schultz in February 2005. Trial Tr. Vol. 3B at 55:21-22.

- Dr. Schultz prescribed Zometa® for Mr. Brodie "to decrease the chances for future skeletal events and delay the next skeletal event." Health Care Record of 02/24/05 (0915-0024 to -0025), Ex. DX-HF-1 (attached as Exhibit 4); Trial Tr. Vol. 3B at 81:19-23.

- Dr. Schultz was aware that ONJ was a possible side effect of Zometa® when he prescribed the drug for Mr. Brodie. Trial Tr. Vol. 3B at 83:5-10.

- Dr. Schultz weighed the risk of ONJ against the benefits before he prescribed Zometa® treatment for Mr. Brodie. Trial Tr. Vol. 3B at 85:6-13.

- Dr. Schultz would still recommend that Mr. Brodie take Zometa® to treat his bony metastases. Trial Tr. Vol. 3B at 85:23-86:2

ARGUMENT

I. Legal Standard for Judgment as a Matter of Law

Judgment as a matter of law is necessary because plaintiff has been fully heard and she has not presented sufficient evidence to carry her burden of proof. *See* Fed. R. Civ. P. 50(a)(1). "Rule 50(a) allows the judge in a jury trial to enter judgment against a party with respect to a claim or defense 'that cannot under the controlling law be maintained or defeated without a favorable finding on that issue,' when the party has been fully heard on the issue and 'there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on the issue.'" *Kinserlow v. CMI Corp*, 217 F.3d 1021, 1025 (8th Cir. 2000) (quoting Fed. R. Civ. P. 50(a)). Though this Court must "draw all reasonable inferences in favor of the nonmoving party," *Reeves*, 530 U.S. at 150, the non-moving party is "not entitled to the benefit of unreasonable inferences or those in conflict with the uncontested facts." *McGreevy v. Daktronics, Inc.*, 156 F.3d

837, 840-41 (8th Cir. 1998) ("A reasonable inference is one which may be drawn from the evidence without resort to speculation. When the record contains no proof beyond speculation to support the verdict, judgment as a matter of law is appropriate.") (quoting *Sip-Top, Inc. v. Ekco Group, Inc.*, 86 F.3d 827, 830 (8th Cir. 1996)); *see also Arabian Agriculture Servs, Co. v. Chief Indus., Inc.*, 309 F.3d 479, 482 (8th Cir. 2002).

II. Plaintiff Has Not Introduced Evidence Sufficient to Submit Her Claims to the Jury.

A. Plaintiff Cannot Show that the August 2004 Zometa® Label Contained an Inadequate Warning.

It is undisputed that the Zometa® label contained four paragraphs of information about ONJ, the exact adverse event that Mr. Brodie claims to have suffered, in two different sections. In Missouri, a warning is adequate as a matter of law where, as here, it warns about the specific adverse event that the plaintiff suffered. *See Wilson v. Lockwood*, 711 S.W.2d 545, 548-49 (Mo. Ct. App. 1986) (warning regarding medical device used for circumcision was adequate as a matter of law where it discussed specific adverse event that occurred); *see also Anderson v. F.J. Little Mach. Co.*, 68 F.3d 1113, 1114-15 (8th Cir. 1995) (affirming district court's conclusion that warning was "legally sufficient" where it warned of potential injury to hands). NPC put this warning in Dr. Schultz's hands; the undisputed evidence shows that he received the Dear Doctor letter and accompanying label. *See Doe v. Miles*, No. ED-75100, 2000 WL 667383, at *17 (Mo. Ct. App. May 23, 2000) (holding it was error for trial court to deny motion for a directed verdict where evidence showed that doctor was aware of the risk of the alleged adverse event). When plaintiff's own oncology expert, Dr. Vogel, received the Dear

Doctor letter, it likewise immediately warned him that spontaneous ONJ was a risk of using Zometa®.

Plaintiff has advanced various arguments about the adequacy of the August 2004 label in this case, including that it does not: (a) state sufficiently that there is a causal relationship between Zometa® and ONJ, and (b) indicate sufficiently that ONJ can occur spontaneously. She further claims that the label was inadequate because it refers to other risk factors for ONJ as being "well documented" in the literature. Even if plaintiff's characterizations of the Zometa® label were true – which they are not[3] – these allegations are not relevant to adequacy given Dr. Schultz's own testimony that he clearly understood ONJ was a potential side effect of Zometa®.

Plaintiff cannot create a submissible case by simply suggesting ways that the label could have been worded differently. She has to show that the label has some flaw that would have made a difference, *i.e.*, that would have been materially important to Dr. Schultz in his decision to prescribe Zometa® for Mr. Brodie. She has failed in that regard.[4]

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[3] It is undisputed that the label contains information about ONJ, and plaintiff has not explained how the warnings she claims should have been given were not "fairly includable in the information disclosed . . . on the package insert in evidence." *Johnston v. Upjohn Co.*, 442 S.W.2d 93, 96 (Mo. Ct. App. 1969).

[4] *See Campbell v. Am. Crane Corp.*, 60 F.3d 1329, 1333 (8th Cir. 1995) (noting that failure to warn theory must be tied to the actual facts of the case); *see also Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1019 (8th Cir. 2004) (affirming grant of summary judgment to defendant in pharmaceutical case where plaintiff put forth no evidence to show why existing warnings were inadequate). Dr. Schultz testified that nothing plaintiff showed to him and nothing that he has learned about ONJ since February 2005 would have changed his decision to prescribe Zometa® for Mr. Brodie, who had an "overwhelming need for Zometa." Trial Tr. Vol. 3B at 85:6-10; 85:23-86:2. *See also Doe*, 2000 WL 667383, at *3 (party is bound by the uncontradicted testimony of its own witness, even testimony elicited on cross examination).

B. Plaintiff Has Failed to Carry Her Burden of Showing Proximate Cause.

If plaintiff had managed to adduce evidence sufficient to create a jury question on the adequacy of the warning, plaintiff then bears the additional burden of showing that an inadequate warning was the proximate cause of Mr. Brodie's injury. *See Menz v. New Holland N. Am., Inc.*, 460 F. Supp. 2d 1050, 1055-56 (E.D. Mo. 2006) *aff'd*, 507 F.3d 1107 (8th Cir. 2007). In this pharmaceutical products liability case, she must carry that burden by showing that Dr. Schultz would have done something differently if he had received a different warning and that the something different would have prevented or mitigated Mr. Brodie's injury. *See Arnold v. Ingersoll-Rand Co.*, 834 S.W.2d 192, 194 (Mo. 1992) (en banc); *Kirsch*, 753 F.2d at 671. Plaintiff has failed to admit sufficient evidence on this point.

1. Plaintiff Cannot Rely On a Heeding Presumption Because She Has Not Shown that Dr. Schultz Was Unaware Of the Risk of ONJ.

Plaintiff purports to rely upon a "heeding presumption" to satisfy her burden of proof on proximate causation, but the "heeding presumption" does not apply to this case. "[A] preliminary inquiry before applying the [heeding] presumption is whether adequate information is available *absent* a warning." *Arnold*, 834 S.W.2d at 194. Before she can implicate the heeding presumption, plaintiff must introduce sufficient evidence from which a jury could find that Dr. Schultz was not aware of the risk of ONJ associated with Zometa®. *Id.* at 194, 197 ("[T]he burden is on plaintiffs to show that lack of knowledge."); *see also Menz*, 460 F. Supp. 2d at 1055-56 (granting summary judgment where "there were no warnings which [defendant] could have given Plaintiff that would have altered his conduct at the time of the accident".) But, Dr. Schultz testified:

> Q. Okay. And at the time that you prescribed Zometa for Mr. Brodie, you knew that ONJ was a side effect, a potential side effect of –
> A. Yes.
> Q. – Zometa? And you still prescribed it?
> A. Yes.

Trial Tr. Vol. 3B at 83:5-10.

Particularly in the context of drugs and medical devices, Missouri courts have repeatedly held that a plaintiff cannot prove proximate cause where the physician was aware of a particular risk associated with the drug or product. *See, e.g.*, *Doe*, 2000 WL 667383, at *16 (holding that plaintiff could not establish proximate cause where "[t]he record fails to establish that during the relevant time period Dr. Bouhasin was not aware of the then-available information regarding the risk[s]" associated with blood product); *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 420 (Mo. Ct. App. 1999) ("Thus, the causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had substantially the same knowledge as an adequate warning from the manufacturer that should have been communicated to him."); *Kirsch*, 753 F.2d at 672 (holding that plaintiff could not carry her burden of showing proximate cause where there was insufficient evidence to show physician's lack of knowledge of risks). Plaintiff has put forth no evidence to show that Dr. Schultz was not aware of the *specific risk* of ONJ associated with the use of Zometa® at the time that he prescribed Zometa® for Mr. Brodie. *See Anderson*, 68 F.3d at 1115-16 (affirming judgment for defendant where the person to whom a duty was owed was already aware of specific risk of injury). Accordingly, the heeding presumption does not apply in this case and plaintiff cannot demonstrate that an inadequate warning was the proximate cause of Mr. Brodie's injury.

2. Even if the Heeding Presumption Applied, It Would Not Be Enough to Carry Plaintiff's Burden in This Case.

Even if the heeding presumption applied, it would not create a genuine issue in this pharmaceutical products liability case. "The presumption that plaintiffs will heed a warning assumes that a reasonable person will act appropriately if given adequate information." *Arnold*, 834 S.W.2d at 194. The inquiry must focus, therefore, on the person who acted, *i.e.*, Dr. Schultz.

In many product liability cases, the "appropriate" course of action is obvious from the circumstances of the case and the jury can determine, without assistance, what the recipient of a warning would do. *See, e.g., Anderson*, 68 F.3d at 1115 (dealing with adequacy of a warning to avoid putting one's hands in a moving pinch roller machine). Courts that have looked at the heeding presumption in the context of a pharmaceutical products liability action recognize, however, that the impact on the doctor's conduct is not obvious. *See, e.g., Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551, 557 (N.D. Tex. 2006) ("Many courts have held that to 'read and heed,' in the context of a learned intermediary, means only that the physician would have incorporated the additional risk into his decisional calculus."); *Ackermann v. Wyeth Pharms., Inc.*, 526 F.3d 203, 212 (5th Cir. 2008) (recognizing that as applied to a physician, heeding only means that physician will consider additional risk); *In re Rezulin Prods. Liab. Litig.*, No. 00-CV-2843, 2004 WL 2029404, at *4 (S.D.N.Y. Sept. 9, 2004) ("[T]he presumption, in those states that have adopted it, presumes only that: the learned intermediary would have incorporated the 'additional' risk into his [or her] decisional calculus.") Accordingly, plaintiff must come forward with additional evidence that Dr. Schultz, having incorporated the additional risk information into his calculus, would not have prescribed Zometa® for Mr.

Brodie. Plaintiff had the opportunity to establish this point when they called Dr. Schultz in their case, but she was unable to do so.

Dr. Schultz testified that in his view, continuing to recommend Zometa® was the right choice for Mr. Brodie regardless of the risk of ONJ, and plaintiff has put forth no contrary evidence. Trial Tr. Vol. 3B at 85:8-10 ("I thought he had an overwhelming need for Zometa more than the risks he had of ONJ."); *id.* at 85:14-86:6 ("Q. Now, has anything been discussed in court today, have you seen anything in the medical literature, anything in the universe of discussions about Zometa that would change your mind about prescribing Zometa for Mr. Brodie? . . . A. If I saw an identical patient today, I would prescribe Zometa because the prostate cancer would be the overwhelming concern of mine.").

Further, even if plaintiff had shown that the "appropriate" course would have been to do something differently, plaintiff must still show, through expert testimony, that the "something different" would have made a difference for Mr. Brodie. *See Delisi v. St. Luke's Episcopal-Presbyterian Hosp.*, 701 S.W.2d 170, 175-76 (Mo. Ct. App. 1985) (though plaintiff showed that doctor should have done something differently, she could not make a submissible case where she had no proof that different action would have prevented injury); *Eberhart v. Novartis Pharm. Corp.*, No. 1:08-CV-2542, 2011 WL 5289372, at *12 (Oct. 31, 2011) (granting summary judgment because even if physician altered her conduct by instructing plaintiff to avoid dental procedure, plaintiff had no evidence that she would have avoided dental procedure and subsequent alleged ONJ). None of plaintiff's experts, including Dr. Marx, have testified that anything could or

should have been done to prevent or mitigate Mr. Brodie's alleged spontaneous ONJ in this case.

C. None of Plaintiff's Purported Factual Issues Is Material to the Outcome of This Case.

Plaintiff will argue that this case should go to the jury because there are factual disputes. However, none of the issues that she raised at trial has any bearing on the outcome of the case. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) ("the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion . . .; the requirement is that there be no *genuine* issue of *material* fact.").

- First, whether Dr. Schultz told Mr. Brodie about the risk of ONJ or recommended that Mr. Brodie have a pre-treatment dental examination when he prescribed Zometa® is immaterial. The relevant issue here is not what *Mr. Brodie* knew about the risk, the relevant question is what *Dr. Schultz* knew about the risk. *See Kirsch*, 753 F.3d at 671 (holding that plaintiff was not entitled to have a jury consider whether defendant was liable for failing to warn her directly under the learned intermediary doctrine). Even, if Mr. Brodie was not warned, "[t]his . . . is not the same as proving that Dr. [Schultz] did not know of the risk." *Id.* at 672.

- Second, whether NPC should have provided a copy of the Expert Panel Recommendations to oncologists is immaterial, because Dr. Schultz testified that none of the language therein would have influenced his prescribing decision. *See* Trial Tr. Vol. 3B at 73:14-25 (he still would

have prescribed Zometa® for Mr. Brodie if he had seen the description of clinical presentation and diagnosis); 74:1-4 (he knew that listed symptoms could be symptoms of ONJ); 74:10-16 (he understood what the signs and symptoms of ONJ were in 2005); 74:24-75:6 (warning about dentures would not have dissuaded him from prescribing); 75:15-76:15 (performed an oral examination every time he saw Mr. Brodie); 85:14-86:2 (nothing that was discussed in court would have changed his decision to prescribe Zometa®).

- Whether the label should have mentioned other "well documented" risk factors is irrelevant here because Dr. Schultz's unimpeached testimony was that the language did not influence his prescribing decision. Trial Tr. at 85:2-13.

- Whether Dr. Schultz would have recommended a pre-treatment dental examination, or discontinued Mr. Brodie's Zometa® during his August 2005 root canal treatment had he been given a different warning also has no bearing on this case. Plaintiff's own expert, Dr. Marx, testified that Mr. Brodie's condition was not caused by a pre-existing dental issue or by his root canal treatment. Trial Tr. Vol. 3A at 79:4-21 (ruled out periodontal disease, dental abscesses, and root canal treatments as contributing factors); *see also id.* at 85:17-21 (Transcript excerpts attached as Exhibit 5).

CONCLUSION

Plaintiff has failed to introduce sufficient evidence to create a jury question on her product liability claims. Accordingly, NPC is entitled to judgment as a matter of law.

January 26, 2012

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have on this 26th day of January 2012 served a true and correct copy of the foregoing Novartis Pharmaceuticals Corporation's Motion for Judgment as a Matter of Law on All Claims by operation of the Court's Electronic Filing System, on the following:

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